

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL NO. 1456

THIS DOCUMENT RELATES TO:

TRACK TWO SETTLEMENT

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

**CLASS COUNSEL’S PROPOSAL TO REDISTRIBUTE THE
TRACK TWO CONSUMER ALLOCATION**

I. INTRODUCTION

At the Track Two settlement fairness hearing held June 13, 2011, Class Counsel suggested that the manner in which the monies allocated to the Class 1 and Class 3 consumers in the proposed settlement should be modified to align the Track Two settlement with the approaches used in the AstraZeneca and BMS settlements. The Track Two distribution formula preliminarily approved by the Court – which is based on consumer out-of-pocket co-pays – did not reasonably reflect each consumer’s damages for the Class drugs. Although we provided the Court with examples at the June 13 hearing, we could not provide the Court with reasonably accurate claims estimates due to the fact that the Class 1 claims period remained open to July 1.

The Claims Administrator, Rust Consulting, Inc. (“Rust”) has provided a more accurate estimate for purposes of considering a more cogent distribution formula. Using these numbers, Class Counsel propose to modify the distribution formula in order to ensure that:

- Class 1 and 3 consumers receive double their actual damages incurred on eligible administrations of Class A drugs;

- Class 1 and 3 consumers receive a flat payment of approximately \$53.28 for all administrations of Class A drug Epogen, for which they did not incur any damage but are providing a release; and
- Class 3 consumers electing the “Easy Pay” refund option receive a full \$35 flat payment.

Under the proposal described herein, the amounts paid to consumers for their eligible Class B drug claims remains the same. Further, the proposal does not entail changing the allocation between consumers and third-party payors (“TPPs”), which presently provides for a gross split of settlement proceeds of 17.5% to consumers and 82.5% to TPPs.¹

We believe that this proposed redistribution formula accomplishes the Court’s goal of linking the distribution methodology to actual damages and providing a premium for the Class A “Heartland Drugs,” consistent with the Court’s prior approval of the AstraZeneca Class 1 settlement and the BMS settlement, as recently modified. The proposed redistribution is supported by Class Counsel and the current and proposed Class Representatives, who respectfully request that the Court approve it.²

II. THE NEED FOR AN ALTERNATIVE DISTRIBUTION PLAN

To review, under the present distribution methodology preliminarily approved by the Court, a “Total Recognized Claim” is calculated for Class 1 consumers and for the Class 3 consumers who chose the “Full Estimation Refund” option instead of the \$35 “Easy Pay” refund option.³ The calculation is made by summing their *out-of-pocket payments* for Class A drugs

¹ Although consumers and TPPs share notice and administration costs, TPPs bear a disproportionate amount of those costs given that (i) the costs are deducted before the consumer/TPP allocation is made and (ii) consumer notice costs were much higher than TPP notice costs.

² Mediation efforts led by Professor Eric Green have not resulted in any agreement with objectors, although we hope that those efforts will continue.

³ Under the Full Estimation Refund Option, a Class 3 consumer must have provided an estimate of their total out-of-pocket expenditures during the Class Period for each Class drug for which they seek reimbursement and at least one form of documentary proof that they incurred a percentage co-pay or cash obligation outside of Medicare Part B. For those Class 3 consumers who chose the “Easy Pay” option,

during the Heartland Period, multiplying the sum by three, and then adding out-of-pocket payments for Class B drugs and Class A drugs outside of the Heartland Period:

$$\begin{array}{ccccc} \text{Out of Pocket} & & & & \text{Out of Pocket Payments} & & & & \text{Total} \\ \text{Payments for Class} & \times 3 & + & & \text{for Class B Drugs and} & = & & & \text{Recognized} \\ \text{A Drugs During} & & & & \text{Class A Drugs Outside} & & & & \text{Claim} \\ \text{Heartland Period} & & & & \text{of Heartland Period} & & & & \end{array}$$

The Total Recognized Claim is then reduced proportionately based on all claims filed.

Importantly, under the foregoing formula, the payment is based on co-pays or cash pays, *which are greater than actual damages*.

Based on the claims experience, Rust has estimated that the pro-rata reduction for Class A drugs results in the payment of approximately 3.37% of the Total Recognized Loss, and about 5.83% of Total Recognized Loss for the Class B drugs. Pro-rata reduction also results in the Easy Pay amount being lowered from \$35 to \$2.04 *See Declaration of Daniel Coggeshall Regarding Estimated Net Consumer Settlement Fund and Estimated Class 1 and Class 3 Consumer Payments for the Track Two Settlement (“Coggeshall Decl.”), ¶¶ 11-12 & Ex. A.*

As the tables below demonstrate,⁴ the present distribution formula results in a mismatch between actual damage and the total estimated payout for Class A drugs. Rust calculated the total estimated damages based on overcharge ratios provided by Dr. Hartman; these numbers appear in the “Total Estimated Damages” column in each table. The column titled “Total Estimated Payout per Current Method” shows what would be paid for each Class A drug under the current distribution methodology, including pro-rata reductions.

For Class 1:

they were only required to certify that they made one or more percentage co-pay or cash payments for one or more Class drugs during the Class Period.

⁴ The tables were compiled from data appearing in Exhibits A and B to the Coggeshall Declaration.

Class A Drug	Total Estimated Damages	Total Estimated Payout Per Current Method
Anzemet	\$1,655,777.93	\$ 343,312.37
Aranesp	156,569.80	1,166,280.53
Epogen	0	5,477,030.85
Ferrlecit	959,720.11	525,822.30
InFed	429,382.82	198,547.06
Neulasta	63,998.73	745,185.92
Neupogen	<u>13,457.54</u>	<u>691,075.57</u>
Subtotal	3,278,906.93	\$9,147,254.61
Double	\$6,557,813.86	

Difference of \$2,589,440 to provide flat payment for Epogen administrations and enhance Easy Pay payment amount

For Class 3:

Class A Drug	Total Estimated Damages	Total Estimated Payout Per Current Method
Anzemet	\$74,240.25	\$19,871.59
Aranesp	43,834.84	86,733.09
Epogen	0	84,275.83
Ferrlecit	17,315.30	6,594.12
InFed	10,772.32	4,357.98
Neulasta	35,673.08	106,239.02
Neupogen	<u>12,288.06</u>	<u>84,901.99</u>
Subtotal	194,223.85	\$392,973.62
Double	\$388,447.70	

Actual damages slightly less than Class A drug availability

When comparing the total estimated damages with the total estimated payout in both tables, we see that some drugs are receiving much less than their actual damage – like Anzemet, Ferlecit and InFed – while the others are receiving much more than their actual damage. Epogen in particular is skewing the Class A claims, even though there are zero damages because Epogen was reimbursed at a statutorily set rate and not based on AWP in Class 1, and even though there are no Class 3 damages due to the low spread.

When the total estimated damages and total payout for Class 1 are compared, the difference is \$2,589,440. This can be used to provide a flat payment for Epogen administrations and to ensure that the Class 3 Easy Pay amount is \$35.

Although the foregoing estimates are not final calculations, they should be sufficiently accurate to use in proposing a redistribution plan.

III. A PROPOSED “REDISTRIBUTION” SCENARIO

In order to align the Class A drug recovery with actual damages and then double those damages, and thereby make the Track Two consumer distribution more consistent with the distribution formulas used in the AstraZeneca and BMS settlements, Class Counsel propose a “redistribution” of the consumer monies. The results of the redistribution proposal are set forth in Exhibit D to the Coggeshall Declaration.

The proposed redistribution accomplishes the following:

1. Class 1 and 3 consumers receive ***double*** their actual damages incurred on eligible administrations of Class A drugs, ***even for administrations outside of the Court’s “Heartland Period.”***
2. Class 1 and 3 consumers receive a flat payment of approximately \$53.28 for all administrations of Class A drug Epogen, for which they did ***not*** incur any damage but for which they are providing a release.
3. Class 3 consumers electing the “Easy Pay” refund option receive a ***full*** \$35 flat payment, instead of \$2.04 under the present pro-ration.

4. It leaves the modest payout calculated under the present methodology the *same* for Class B drugs. Given the challenges posed in identifying generic drugs (due to interchangeable J-Codes) and reimbursement schemes based on median AWP (for Medicare) and maximum allowable costs (outside of Medicare), we do not believe that enhanced payouts for the Class B drugs are necessary. Further, there is very little spread marketing evidence for the Class B drugs. These factors have led Class Counsel to conclude that Class B damages are *de minimis*.

Under this proposal, *all* Class 1 and Class 3 consumers will receive more than their actual damages for their Class A drug administrations and will receive a modest amount for Epogen and Class B administrations. The Class 1 and Class 3 splits would be as follows:

- Class 1 will receive a total of approximately **\$12,311,760.32** – \$6,557,813.83 for Class A drugs, \$2,098,046.52 for Epogen and \$3,655,899.98 for Class B drugs. *See Coggeshall Decl., Ex. D.*
- Class 3 will receive a total of approximately **\$1,251,901.64** – \$388,447.69 for Class A drugs, \$14,492.16 for Epogen, \$474,468.75 total in \$35 Easy Pays and \$374,493.04 for Class B drugs. *See Coggeshall Decl., Ex. D.*

Even though they will receive double their actual damages for Class A drug purchases, approximately 38,253 claimants will receive less under this proposal than they would under the present distribution formula. Coggeshall Decl., ¶ 17. The Court would likely have to send another notice to these claimants, advising of the change and providing another period for comment.

Class Counsel have reviewed the proposed redistribution plan with the Class Representatives, and they approve. Declaration of Steve W. Berman in Support of Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation, ¶ 2.

IV. MISCELLANEOUS FOLLOW-UP

During the June 13, 2011 Track Two fairness hearing, the Court requested that counsel provide a brief history of the approval process related to the Track Two Settlement in order to refresh the Court's recollection, particularly given that a previous Track Two approval hearing had been held in April 2009. June 13, 2011 Hearing Tr. at 34. The Court also requested

information concerning the results of a supplemental notice program to cash payors, a notice that the Court ordered be provided after the April 2009 hearing. *Id.* at 35. Lastly, the Court sought confirmation that the Class 3 claims deadline appearing on the settlement website is correct. *Id.* at 80. Class Counsel respond to each of these items below.

A. Procedural History of the Track Two Settlement

The Court granted preliminary approval of the Track Two Settlement on July 2, 2008. Dkt. No. 5426. That order contemplated that notice to all Classes would be complete by the fall of 2008 and scheduled a final approval hearing for December 16, 2008. In November 2008, Class Counsel filed a report with the Court explaining that although publication and mailed notice to TPPs was complete and publication notice to Class 3 consumers had been accomplished, a letter of clarification was being sent to TPPs concerning the drug list attached to the original mailed notice. Further, data had not yet been received from ISHPs or CMS in order to send direct mail to Class 3 and Class 1 consumers, respectively. *See* Dkt. Nos. 5703, 5754. A status conference was held on December 16, 2008, and the Court scheduled a final fairness hearing for April 27, 2009. Dkt. No. 5828.

In anticipation of the April 27, 2009 fairness hearing, Class Counsel submitted papers with the Court seeking approval of the Settlement. *See* Dkt. Nos. 5934-35. Although notice had yet to be provided to Class 1 because CMS had not produced the necessary information, Class Counsel informed the Court that both publication and direct mail notice to TPPs and to Class 3 consumers was complete. Objections to the Settlement were received (*see* Dkt. Nos. 5738, 5921, 5947, and 5971), and Class Counsel responded in writing to each objection (*see* Dkt. No. 6003). During the April 17, 2009 hearing, the Court heard from various objectors to the Settlement and expressed misgivings about the clarity of the written notice provided to Class 3 consumers who

paid cash for their drugs. The Court ordered a second round of notice directed specifically at cash paying consumers in Class 3. April 27, 2009 Hearing Tr. at 85.

In October 2009, Class Counsel submitted the form and manner of additional notice to Class 3 cash payors. Based on previous experience with AWP settlements, Kinsella Media recommended that cable television ads and internet banner ads be used instead of direct mail notice because they were more effective at driving claims. Class Counsel also advised that they were continuing to work with CMS to obtain data related to Class 1. Dkt. No. 6581. The Court approved the additional notice to Class 3 and scheduled a fairness hearing for February 2, 2010. Dkt. No. 6591. The additional notice to cash payors in Class 3 was completed on December 14, 2009.

On December 4, 2009, Class Counsel still had not received CMS data sufficient to send notice to Class 1 consumers. Consequently, Class Counsel filed a motion to modify the pending schedule. The Court granted the motion and ordered all of the pending dates related to consumer notice and claim filing, as well as the February 2, 2010 fairness hearing, suspended. *See* Dkt. Nos. 6736, 6760. It was contemplated that when the data was obtained from CMS, Class Counsel would file a revised schedule for notice to Class 1 and a fairness hearing with the Court.

During the balance of 2010, while issues related to notice and final approval of the BMS settlement were also being heard by the Court, Class Counsel continued to seek data from CMS related to Class 1 consumers in the Track Two settlement. The Court then provided a helping hand. On November 19, 2010, in response to an Order of the Court requiring attendance by the CMS data vendor, the Court heard testimony from an employee of the CMS vendor concerning production of the necessary data. On November 30, 2010, the Court ordered CMS and its vendor to produce the required data by December 15, 2010. CMS finally complied, producing half of

the required data in mid-December and the balance of the data on December 28, 2010. Dkt. Nos. 7358, 7370.

The CMS data revealed approximately 19 million potential Class 1 consumers. On December 31, 2010, Class Counsel filed a status report with the Court outlining the expense associated with direct mail notice to all 19 million potential Class 1 members along with potential alternatives to direct mail notice. On January 7, 2011, the Court directed Class Counsel to proceed with direct mail notice to the 2.2 million individuals identified in the CMS data as having Class A drug administrations and a national media notice program directed at Class 1 members with Class B drug administrations. On February 9, 2011, the Court approved the revised notice plan and schedule for final approval of the Settlement, and established a fairness hearing on June 13, 2011. Dkt. No. 7406.

B. Notice to Class 3 Cash Payors

As noted, supplemental notice to cash payors was ordered by the Court and completed on December 14, 2009. It is not possible to provide the Court with an exact number of Class 3 consumer claimants who (i) were not covered by some form of insurance and (ii) paid only cash for their Track Two drugs. The reason is that Class 3 consumers' insurance status was not requested as part of the claim form. However, given the timing of the supplemental notice directed at Class 3 cash payors, it is possible to gauge reaction.

Prior to the supplemental notice to cash payors in December 2009, Rust had received a total of 19,782 Class 3 claim forms. In the period after supplemental notice until today, the administrator has received an additional 1,198 Class 3 claims. Reaction to the supplemental notice can also be evaluated based on the number and timing of calls received by Rust's settlement call center. The following chart indicates the number of calls received by the call

center in the period prior to, during and after the supplemental notice to cash payors in December 2009:

Date Range	Number Of Calls
Sept. 1, 2009 thru Nov. 30, 2009	275
Dec. 1, 2009 thru Dec. 31, 2009	1,211
Jan. 1, 2010 thru Jan. 30, 2010	131

These statistics suggest that there was a quantifiable – though very modest – reaction to the supplemental notice provided to cash payors in December 2009.

C. Class 3 Claims Deadline on the Website

The Court inquired about language on the portion of the settlement website dedicated to Class 3 claims indicating that the claims deadline for filing of Class 3 claims was May 1, 2009.

The full language included on the Class 3 portion of the website is as follows:

Due Fate for Filing a Claim: ***The deadline has passed.*** To be considered timely claims needed to be postmarked on or before May 1, 2009. ***However if you have not yet filed a claim you may still do so although the claim will be deemed “late” and will require court approval to be paid if otherwise eligible.*** [Emphasis in the original].

See <http://www.awptrack2settlement.com/consumerclass3.htm>. A review of the history of the Class 3 website and changes in Court approved filing dates for Class 3 consumers indicates that in fact the language on the Class 3 webpage should indicate that to be considered timely claims needed to be postmarked on or before February 1, 2010, not May 1, 2009. This inadvertent error is of no consequence however, as detailed below.

The website was created on July 29, 2008. The original due date for filing of Class 3 claims was listed as January 31, 2009. See Preliminary Approval Order, Dkt. No. 5426. In response to the Court’s January 7, 2009 Order resetting dates related to the Settlement, the due

date for Class 3 claims as listed on the website was changed to May 1, 2009. Dkt. No. 5828. When the Court ordered supplemental notice to be sent to cash payors in December 2009, the website was changed to reflect the revised due date for Class 3 claims of February 1, 2010. Dkt. No. 6591. In December 2009, in response to the Court's order suspending all dates for notice and approval of the Settlement (Dkt. No. 6760), language was added to the Class 3 webpage as follows:

Please note that the relevant deadlines for filing a claim, an objection to the settlement or a request for exclusion have been temporarily suspended until further notice. Consumers can still file claims during this period and are urged to do so.

On February 12, 2011, the Court established new deadlines for Class 1 consumer claims after CMS Class 1 data was received. Dkt. No. 7406. Because the dates established for Class 1 claims did not apply to Class 3 consumers, the current language concerning the May 1, 2009 Class 3 deadline was added to the Class 3 page. This was an error. The date that should have been listed as pertaining to Class 3 claims was the last date established for Class 3 claims – February 1, 2010. *However, the addition of this language in February 2011, more than a year after the actual February 1, 2010 deadline, cannot be said to discourage Class 3 claims.* At all times, the website encouraged Class 3 claimants to file a claim, even if considered late. In addition, Rust employees handling questions from potential claimants also encouraged the filing of Class 3 claims, irrespective of the filing in relation to Court approved filing deadlines specific to Class 3.

V. CONCLUSION

Class Counsel believe that the foregoing redistribution proposal is fair and reasonable and request that the Court approve both it and the Track Two settlement.

DATED: July 5, 2011

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on July 5, 2011, I caused copies of *Class Counsel's Proposal to Redistribute the Track Two Consumer Allocation*, to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
Steve W. Berman